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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/502,049	STAHL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 May 2009.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 32-53 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 32-53 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

The amendment filed 5/18/2009 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-31 have been canceled.
2. New Claims 32-53 have been added.
3. Remarks drawn to claim objections and rejections under 35 USC 112, first and second paragraphs, obviousness-type double patenting, 102 and 103.

The following objection and rejections of record have been withdrawn since Applicants' amendment with canceling claims 1-31 has been found persuasive:

- a) The objection to claim 24 under 37 CFR 1.75 (c) as being of improper dependent form for failing to further limit the subject matter of a previous claim, and
- b) The rejection of Claims 14-17, 20-23, 25 and 27-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a method of preventing infections using the carbohydrate of formula I and a composition further comprising active agents(s) and ingredients, and
- c) The rejection of Claims 14-17 and 20-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, and
- d) The rejection of Claims 24 and 31 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 12-13 of copending Application No. 10/148,193('193) and the rejection of Claims 24 and 31 on the

ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Patent No. 6,576,251 ('251 patent), and

e) The rejection of Claims 29 and 31 under 35 U.S.C. 102(b) as being anticipated by Gilbert et al (WO 00/46379; document cited in IDS of 30 July 2004) and the rejection of Claims 14-17 and 20-31 under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al (WO 00/46379; document cited in IDS of 30 July 2004).

Claims 32-53 are pending in the case.

### ***Claim Objections***

Claim 53 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 53 depends from itself.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites structural formula (I) in which V is defined as an OH or carbohydrate residue or a carrier T and the carbohydrate or carrier is further defined as formula (II). This

means that that the carrier and carbohydrate residue are one and the same, since formula (II) is identical to (I). The term carrier is also defined by the letter T, which means that it could be any moiety. It is not clear what applicants intend. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation carrier T, and the claim also recites carbohydrate residue, which is the narrower statement of the range/limitation. This lack of clarity is also seen in claims 40 and 42. Clarification is needed.

Claim 33, which depends from claim 32, recites that the carrier T is a peptide, a protein, a polymer or a biopolymer. But according to parent claim 32 the carrier is defined by formula (II). It is not clear what applicants intend. Also, according to the recitation of the parent claim 32, V can be a carbohydrate residue or a carrier T. But according to the recitation of dependent claim 33, the compound can have both the carbohydrate residue and the carrier T. This is not seen to further limit the parent claim. A broad range or limitation together with a narrow range or

limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 33 recites the broad recitation polymer, biopolymer, and the claim also recites peptide, protein, which is the narrower statement of the range/limitation.

Claim 42 recites, 'wherein formula I has at least one carbohydrate unit of formula II'. Formula I has the structure recited formula II in it. It is not clear what applicants intend.

Claim 50 recites the terms probe food. It is not clear what applicants intend by this recitation. For the purpose of prosecution the claim is examined as drawn to food.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 42 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 12-13 of copending Application No. 10/148,193('193). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claim 42 is drawn to a food, dietetic or pharmaceutical composition comprising the sialylized carbohydrates of formula (I).

Claims 1, 3-7 and 12-13 of the copending '193 application are also drawn to the same type of compositions comprising of the same monomeric carbohydrate units that are present in formula (I) in instant claim 42 (see also monomeric saccharide units recited in copending claim 3).

Claims 1, 3-7 and 12-13 of '193 differ from the instant claims in that the instant claims can have a carrier. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the carbohydrates of the instant composition could be successfully employed in the composition of '193.

In determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. In the instant case, '193 teaches the use of each of the monosaccharide residues that applicant claims in the instant application. Although the claims of '193 also employ several other saccharide residues, one of ordinary skill in the art would readily recognize that the scheme taught by '193 could be employed in the instant composition too. The use of known members of classes of agents in compositions to make a similar type of composition taught in the prior art is not seen to render the instantly claimed composition unobvious over the art. Once the general scheme and the agents used has been shown to be old, the burden is on the applicant to present reason or authority for believing that the use of an additional carbohydrate residue or a carrier would affect or alter the nature of the product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 42 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Patent No. 6,576,251 ('251). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claim 42 is drawn to a food, dietetic or pharmaceutical composition comprising the sialylized carbohydrates of formula (I).

Claims 1-10 of '251 are drawn to a food, dietetic or pharmaceutical composition comprising carbohydrate mixtures in a bound form, wherein the mono, oligo or polysaccharides are composed of units that are also seen in formula (I) instant claim 42 also I a bound form.

Claims 1-10 of '251 differ from the instant claims in that the instant claims do not specifically recite the presence of fucose. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the carbohydrates of the instant composition could be successfully employed in the composition of '251.

In determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. In the instant case, '251 teaches the use of each of the monosaccharide residues applicant claims in the instant application. Although the claims of '251 also employ fucose, one of ordinary skill in the art would readily recognize that the scheme taught by '251 could be employed in the instant composition too. The use of known members of classes of agents in compositions to make a similar type of composition taught in the prior art is not seen to render the instantly claimed composition unobvious over the art. Once the general scheme and the agents used has been shown to be old, the burden is on the applicant to present reason or authority for believing that the use of an additional carbohydrate like fucose would affect or alter the nature of the product.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-35, 37-40 and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Iosa (BE 1006598, newly cited).

Iosa teaches the treatment of genital herpes, a viral infection via administration of compositions comprising gangliosides, their salts or esters as active ingredients, especially the gangliosides GM1, GD1a, GD1b and GT1b in combination with a vehicle or excipient (see English Abstract; the patent at page 8, lines 24-33; page 23, lines 4-9). One of the embodiments of the instant method is the administration of the gangliosides GT1b in the said method of treatment (limitations of claims 32, 33(i), 34, 35, 37-genital tract, 38-pharmaceutical, 39, 40-gangliosides). Example 2 (at page 17 of the patent) teaches the treatment of a human patient who is 52 years old (elderly patient as in instant claim 53) with herpes (viral infection; treatment of viral infection in genital tract, limitation of claim 52). This teaching of Iosa is seen to meet the limitations of the said instant claims.

Claims 42-45, 47 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated Gilbert et al (WO 00/46379, of record).

Gilbert et al teach a carbohydrate comprising (labeled GT1a-, the saccharide sequence at the bottom in Figure 4), which has all the components as recited in instant formula (I). It also has a neuraminic acid-5-acetate (NeuAc, acyl derivative) attached to the galactose (on the right). This is the same as the Hex attached to X in instant formula (I), wherein Hex is Galactose (Gal) and X is Neuraminic acid –5-acetate. The glucose moiety on the right side of the sequence is the carbohydrate residue or the carrier as instantly claimed. In addition to this Gilbert also teaches gangliosides GD1a, GT1b and GT1c (page 40, Table 1), which are also seen to fit instant

formula (I). Gilbert teaches pharmaceutical compositions of his compounds suitable for different modes of administration (limitations of claims 42, 44, 45 and 47. The compositions include other agents/auxiliaries like buffers tonicity adjusting agents (limitations of claim 43). Gilbert teaches a composition for oral administration comprising the gangliosides of his invention dissolved or suspended in water (page 42, lines 1-6). This constitutes a composition in the form of a beverage as in instant claim 50.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34, 36, 41 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iosa (BE 1006598, newly cited) in view of Gilbert et al (WO 00/46379, of record).

Isoa's and Gilbert's teachings are as above. Isoa teaches that a dosage of 40-100mg of the active agent in one or more dosages (see English abstract and Example 2). However, both Isoa and Gilbert do not specifically teach a method treating an infection via administration of a composition comprising the gangliosides GD1a and GT1c as in instant claim 34, the dosage of 1mg/kg of body weight as recited in claim 36 and the method of treatment of treating an infection in of the gastrointestinal tract in a human as in claims 41 and 52 method of treatment of bacterial infections as in claim 51.

But one of skill in the art reading the teachings of Isoa and Gilbert will recognize that the related gangliosides GD1a and GT1c have the potential for use in methods of treatment as instantly claimed including bacterial infections since their use in the treatment of a variety of conditions is suggested by Gilbert (page 41, lines 20-26).

It would have been obvious to one of skill in the art at the time the invention was made to make the carbohydrates and derivatives of instant formula (I) and their compositions and use them in a method of treatment of infections as instantly claimed since the use of carbohydrates that are structurally close to instant formula (I) and its composition is suggested in the prior art for treating viral infections. Since Gilbert teaches compositions for different modes of

administration it includes oral administration too. One of ordinary skill in the art would expect oral administration of the active agents to treat infection in the gastrointestinal tract also.

One of skill in the art would be motivated to use the compounds/compositions as instantly claimed since they are close structural analogs and would look for other such analogs with a high therapeutic index and would also expect them to work with a reasonable expectation of success. Obviousness based on similarity of structure and function entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties. Where prior art compound essentially brackets the claimed compounds and are well known agents for treating infections, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new agents that are close structural analogs. *In re Payne*, 606 F. 2d 303, 203, USPQ, 245, 254-55 (C.C.P.A. 1979). Applicants also admit in the instant specification (page 10, lines 19-22) the gangliosides that are encompassed by the instant claims are well known compounds. These are also taught by the prior art above.

Claims 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al (WO 00/46379, of record) in view of Muller et al (Angew. Chem. Intl. Ed. 1993, 32, 477-502, newly cited).

Gilbert et al's teaching is as above. However, Gilbert does not specifically teach a composition wherein the second carbohydrate is bound via a carrier (claim 48), wherein the carrier is polyhydroxybutanoic acid (claim 49).

Muller et al, drawn to polyhydroxybutyric acid (same as polhydroxybutanoic acid), teaches that it is used in slow release compositions since it is biocompatible (page 490, right

column, last paragraph through page 491, left col., first paragraph). This means that the active agents taught by Gilbert (and instantly claimed) can be made into a composition wherein the carbohydrate is bound to a carrier like polyhydroxybutanoic acid.

It would have been obvious to one of skill in the art at the time the invention was made to make the carbohydrates and derivatives of instant formula (I) and their compositions wherein the carbohydrate is bound to a carrier like polyhydroxybutanoic acid since such is suggested in the prior art.

One of skill in the art would be motivated to use the compounds/compositions as instantly claimed since the use of carriers like polyhydroxybutanoic acid is well known and is also biocompatible as taught by Meuller. Biocompatibility of a carrier is an important property for use of a carrier in compositions.

#### ***Response to Applicants Arguments***

1. Applicants have presented arguments for the rejection of claims 24 and 31 under obviousness type double patenting, both of which have been cancelled. The Examiner's response is with regard to the rejection of claim 42 as above. Claim 42 is seen to be the same as cancelled claim 24.

Regarding the obviousness-type double patenting rejection over claims 1, 6 and 9-10 of the '251 patent applicants have argued that claims of the '251 is drawn to a carbohydrate mixture having mono-, oligosaccharides and polysaccharides in varying ratios. The instant claims do not recite the features recited in '251.

This is not found to be persuasive. The '251 patent is drawn to a composition comprising monosaccharide units in as instantly claimed, including bound forms of the carbohydrate units that also have polysaccharides. Since no specific bound form is recited in the '251 patent it is seen to include any sequence of bound forms including instant structure I. The instant claims also recite comprising including a carbohydrate residue for the unit V in instant formula I. This recitation is not seen to exclude fucose. Ratios of the components in a composition can be adjusted. The instant claims are rendered obvious.

Regarding the obviousness-type double patenting rejection over claims 1, 3-7 and 12-13 of the co-pending U.S. Application No. 10/148,193 ('193) applicants argue that the oligosaccharide mixture of the '193 application are obtained from animal milk and have specific ratios of the neutral to acidic oligosaccharides. The instant invention does not use carbohydrates obtained from animal milk and does not recite the specific ratios required by the claims of '193.

Applicants' arguments are not found to be persuasive. Claim 1 of '193 is drawn to a composition comprising oligosaccharide mixtures made up of two or more monosaccharide units. The monosaccharides recited in claim 3 of '193 are present in the oligosaccharide of the instant invention too, including sialic acid. The oligosaccharide mixture of '193 is seen to include any sequence of bound forms including instant structure I. Ratios in a composition can be adjusted. The source of the carbohydrates is not given patentable weight. Applicants have not shown how the instant carbohydrates are patentably distinct from those recited in '193. The instant claims are rendered obvious.

***Conclusion***

Claims 32-53 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623